HIVOX

HIVOX BIOTEK INC
8/F, No.98 Shingde Road Sanchong City Taipei 241 Taiwan ROC
Phone: +886 2 8511 2668 Fax: +886 2 8511 2669

SUMMARY OF SAFETY AND EFFECTIVENESS for TENS & EMS

510(k) : **K092448**

MAR 3 0 2010

DATE OF SUBMISSION: July 27, 2009

SUBMITTER:
HIVOX BIOTEK INC.
8F, No.98, Shinde Road,
Sanchong City, Taipei, 24158, TAIWAN
TEL: 886-2-85112668 FAX:886-2-85112669
Email: ceirs.jen@msa.hinet.net

ESTABLISHMENT REGISTRATION NO: 9611558

OFFICIAL CONTACT:
Dr. JEN, KE-MIN
NO 58, Fu-Chiun Street,
Hsin-Chu City, 30067, TAIWAN
TEL: 886-3-5208829 FAX:886-3-5209783
Email: ceirs.jen@msa.hinet.net

TRADE NAME: HIVOX Electric Stimulator TENS & EMS, HD2

COMMON/USUAL NAME: Transcutaneous Nerve Stimulator & Electric Muscle Stimulator

CLASSIFICATION NAME: Transcutaneous Nerve Stimulator

REGULATION NUMBER: GZJ, Class II, 882.5890

SECONDARY PRODUCT CODE: IPF, Class II, 890.5850

PREDICATED DEVICE:
MEDIHIGHTEC Medical Co., Ltd.
TENS/EMS Combo, EMS, TENS
K082514

K092448

HIVOX

HIVOX BIOTEK INC

8/F, No.98 Shingde Road Sanchong City Taipei 241 Taiwan ROC

Phone: +886 2 8511 2668 Fax: +886 2 8511 2669

Intended Use:

For TENS programs: The device is an electrical nerve stimulator indicated for use for pain relief by applying an electrical current to electrodes on a patient's skin to treat pain. In particular, this device is indicated for use for (1) Symptomatic relief of chronic (long term) intractable pain, and (2) adjunctive treatment in the management of post-surgical and post-traumatic pain problems.

For EMS programs: The device is an electrical powered muscle stimulator indicated for medical purpose to repeatedly contract muscles by passing electrical currents through electrodes contacting the affected body area. In particular, this device is indicated for use for (1) Relaxing muscle spasms, (2) Increasing local blood circulation, (3) Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis, (4) Muscle re-education, (5) Maintaining or increasing range of motion, and (6) Preventing or retarding disuse atrophy.

Description of Device:

The HIVOX Electric Stimulator TENS & EMS, HD2 generates small pulses of electrical current. Delivered along lead cables to electrodes placed on your skin, these pulses pass through the skin and activated underlying nerves. The relief from chronic and acute pain that the HD2 can provide results from this electrical stimulation.

Performance Tests Submitted:

The relevant standards including:

1. IEC/EN 60601-1 : Medical electrical equipment Part 1. General requirements for safety, 1996.
2. IEC/EN 60601-1-2 : Medical electrical equipment, Part 2. Electromagnetic compatibility – Requirements and tests, 2004.
3. IEC/EN 60601-2-10 : Medical electrical equipment Part 2.Safety of Nerve and Muscle Stimulators, 1987.

Non-Clinical Tests Submitted:

The HIVOX Electric Stimulator TENS & EMS, HD2 has been tested in accordance with applicable standards for medical device electrical safety, electromagnetic compatibility, and the particular requirements for safety of nerve stimulators.

Accessories also meet safety requirements: 510(k) electrodes are specified, and the patient cable utilizes shrouded connectors to meet lead wire safety requirements.

System level testing including waveform testing was performed in combination the HIVOX Electric Stimulator TENS & EMS, HD2.

Clinical Tests Submitted:

None

Conclusion:

As the product description and tests as above, the new device: HIVOX Electric Stimulator TENS & EMS, HD2 is as safe and effective as, and the function in a manner equivalent to the predicate device: MEDIHIGHTEC TENS/EMS Combo, EMS, TENS, K082514.

Thus the new device is substantially equivalent to the predicate devices in this aspect.

K092448

HIVOX

HIVOX BIOTEK INC

8/F, No.98 Shingde Road Sanchong City Taipei 241 Taiwan ROC

Phone: +886 2 8511 2668 Fax: +886 2 8511 2669

Comparison for Predicate Device & Subject Device

Comparison Areas	**NEW DEVICE**	*PREDICATE DEVICE*
510(k) number	**K092448**	***K082514***
Manufacturer	HIVOX Biotek Inc	*Medihightec Medical Co. Ltd.*
Device name	HD2 TENS & EMS	*MH8000/6000* *TENS/EMS Combo*
Power source	DC 4.5V (AAA Battery x 3)	*One DC 9V battery*
Channels Synchronous Reciprocal	SAME	*2* *YES* *YES*
Computerized	SAME	*No*
Software provided	SAME	*No*
Constant current	No	*YES*
Constant voltage	YES	*No*
Max output voltage (V_p ±20%)	24.0V ±20% @ 500 Ω load	*20.4V±20% @500 Ω load (40.8 V_{p-p})*
Max output current (mA ±20%)	48.0mA ±20% (500 Ω load)	*40.8 mA±20% (500Ω load) (81.6 mA, $_{p-p}$)*
Pulse Width (μs)	250 μs (fixed)	*50~300 μs*
Maximum Frequency	2~120.2 Hz (adjustable)	*2~150 Hz (adjustable)*
Max phase charge	□12.0 μC @ 500 ohms load	*24.0 μC @ 500 ohm*
Maximum Current Density	0.59 mA/cm^2 @500Ω	*1.06 mA/cm^2 @500Ω*
Maximum Power Density	0.014 W/cm^2 @500Ω	*2.4 m W/cm^2 @500Ω*

K092448

HIVOX

HIVOX BIOTEK INC

8/F, No.98 Shingde Road Sanchong City Taipei 241 Taiwan ROC

Phone: +886 2 8511 2668 Fax: +886 2 8511 2669

Comparison Areas	**NEW DEVICE**	***PREDICATE DEVICE***
Channel isolation	SAME	*YES*
Line current isolation	SAME	*N/A*
Patient override control method	SAME	*YES*
Burst mode	SAME	*YES*
Housing material and construction:	SAME	*Plastic material*
Standards:	SAME	*IEC 60601-1:1988* *EN 60601-1-2:1990*
Timer setting Automatic shut off	SAME 2 minutes	*YES (05~90Min)* *30 Sec*
Automatic overload trip current/voltage level	N/A	*YES*
Automatic no load trip	N/A	*YES*
Indicator display Unit functioning: Low battery indicator: Voltage level:	Power ON Yes NO	*Power ON, Vpp* *NO* *YES*
Weight (unit)	105 g w/o Battery	*162 grams w/ battery*
Dimensions (unit)	120 x 52 x 17 mm	*136 x 70 x 27 mm*
Size of electrode	Carbon silicon of 45x45 mm	*Irregular: 10x15cm*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Hivox Biotek Inc.
c/o Dr. Ke-Min Jen
8F, No. 98, Shinde Rd., Sanchong City
Taipei Hsien
China (Taiwan) 24158

MAR 3 0 2010

Re: K092448
Trade/Device Name:
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: GZJ, IPF
Dated: March 12, 2010
Received: March 19, 2010

Dear Dr. Jen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kevin Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K092448

Device Name: HIVOX Electric Stimulator TENS & EMS, HD2

Indications for Use :

The TENS programs of HIVOX Electric Stimulator TENS & EMS, HD2:
The device is an electrical nerve stimulator indicated for use for pain relief by applying an electrical current to electrodes on a patient's skin to treat pain. In particular, this device is indicated for use for (1) Symptomatic relief of chronic (long term) intractable pain, and (2) adjunctive treatment in the management of post-surgical and post-traumatic pain problems.

The EMS programs of HIVOX Electric Stimulator TENS & EMS, HD2:
The device is an electrical powered muscle stimulator indicated for medical purpose to repeatedly contract muscles by passing electrical currents through electrodes contacting the affected body area. In particular, this device is indicated for use for (1) Relaxing muscle spasms, (2) Increasing local blood circulation, (3) Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis, (4) Muscle re-education, (5) Maintaining or increasing range of motion, and (6) Preventing or retarding disuse atrophy.

Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of ~~CDRH~~, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K092448